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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,544	09/22/2006	Reiji Kannagi	1680/12	4640
25297 7590 12/31/2008 JENKINS, WILSON, TAYLOR & HUNT, P. A. Suite 1200 UNIVERSITY TOWER 3100 TOWER BLVD., DURHAM, NC 27707				
EXAMINER NATARAJAN, MEERA				
ART UNIT		PAPER NUMBER		
1643				
MAIL DATE		DELIVERY MODE		
12/31/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/568,544

**Applicant(s)**

KANNAGI ET AL

**Examiner**

MEERA NATARAJAN

**Art Unit**

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's amendments in the reply filed on 10/21/2008 is acknowledged and entered into the record.
2. Accordingly, Claims 1-10 are pending.
3. Claims 7-10 are withdrawn as being drawn to non-elected inventions.
4. Claims 1-6 will be examined on the merits.

***Claim Rejections Maintained - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Rejection of Claims 1-6 under 35 U.S.C. 102(b) as being anticipated by Streeter et al. (JCB, Vol. 107, pp.1853-1862, Nov. 1988) as evidence by Hemmerich et al. (Immunity, Vol 15, pp.237-247, August 2001) is maintained for the reasons of record.
7. The claims are drawn to a method for examining colorectal cancer and colorectal adenoma comprising assaying the reactivity of an antibody to tissues, body fluid or feces of patients, or extracts thereof, wherein said antibody is MECA-79 (commercially available from BD Pharmingen) and reacts with an antigen that is present in cells expressing HEC-GlcNAc6ST gene encoding GlcNAc-6-sulfotransferase.
8. Streeter et al. teach a method of staining tissue from the small intestine and colon with the MECA-79 antibody (see Figures 1-3). Binding of MECA-79 to its antigen

which is present in cells expressing HEC-GlcNAc6ST gene encoding GlcNAc-6-sulfotransferase would be an inherent feature of the antibody and any method in which the antibody was used to stain tissue sections/samples would inherent perform the method claimed. Hemmerich et al. further support this inherency by disclosing staining of tissue samples expressing HEC-GlcNAc6ST by the MECA-79 antibody (see Figure 5).

9. Applicant argues that Streeter et al. does not teach a method that examines colorectal cancer or colorectal adenoma and therefore does not anticipate the claims. This argument has been carefully considered but not found persuasive. As stated in the original rejection (and above), Streeter et al. teaches a method a staining tissue from the small intestine and colon (Peyer's patches) with the MECA-79 antibody. Figures 1-3 show staining of tissues after contacting the tissue with the MECA-79 antibody. The MECA-79 antibody would only bind where the antigen is present, which as the claim recites in cells that express HEC-GlcNAc6ST gene and not in cells expressing GlcNAc6ST-1 or I-GlcNAc6ST. Therefore, Streeter et al. would be inherently identifying colorectal cancer and colorectal adenoma in the tissue samples stained. The rejection is therefore maintained.

***All other rejections are withdrawn in view of Applicants amendments in the reply filed on 10/21/2008.***

***Conclusion***

10. Claims 1-6 are rejected.
11. No Claim is allowed.
12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MEERA NATARAJAN** whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

/Larry R. Helms/  
Supervisory Patent Examiner, Art Unit 1643